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EXAMINER	
MAHYERA, TRISTAN J	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,045	ADIN ET AL	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,14 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 14 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicants' Remarks and Amendments filed 8/7/2008 is acknowledged.

Status of Claims

Claims 1-9, 14 and 19-21 are pending. Claims 10-13 and 15-18 have been cancelled. Claims 1-9 and 14 have been amended. Claims 19-21 are new. Claims 1-9, 14 and 19-21 are examined on the merits.

Response to Arguments and Amendments

Applicant's arguments filed 8/7/2008 regarding the remarks and amendments have been fully considered but are moot in view of the new grounds of rejection necessitated by amendment. The amendment to claim 1 adds the new limitation requiring the inactive ingredient to be amorphous, which was not originally claimed and succeeds in overcoming WEISMAN, thus the claim rejections under 102 and subsequently 103 are hereby **withdrawn**.

Applicants' further traverse the double patenting rejection by arguing the composition claims of WEISMAN do not have any claim limitations directed to an inactive ingredient. In light of the amendment to further limit and distinguish the instant claims by the addition of an amorphous inert inactive, the double patenting rejection relying solely on WEISMAN is hereby **withdrawn**, however, a new ODP rejection has been added.

Claim Rejections - 35 USC § 102

The rejection of Claims 1-3, 9 and 14 under 35 U.S.C. 102(e) as being anticipated by WEISMAN et al. (US 6,734,195 see PTO-892) is hereby **withdrawn** in light of the amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of Claims 4-8 under 35 U.S.C. 103(a) as being unpatentable over WEISMAN in view of STRAUB et al (US 2002/0142050 see PTO-892) is hereby **withdrawn**.

Claims 1-9, 14 and 19-21 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over APPEL et al (EP 1027887 see PTO/SB/08) in view of SEBHATU et al. (Relationships between the effective interparticulate contact area and the tensile strength of tablets of amorphous and crystalline lactose of varying particle size, 1999, see PTO-892).

APPEL teaches a controlled release dosage composition that comprises a solid amorphous substantially homogeneous dispersion of a low solubility drug in a concentration-enhancing dispersion polymer where a major portion of the drug, i.e., at least about 60%, is amorphous (as opposed to crystalline). See p[0010]:instant claim 1. Up to at least about 90% of the drug is taught to be amorphous. See e.g. p[0010]. The amorphous solid is in the solid form of a tablet, powder, bead or multiparticulate. See e.g. p[0012], [0044] and [0073]: instant claims 1 and 19. The amorphous active pharmaceutical ingredient is specific taught to be the anti-Alzheimer agent donepezil (i.e. donepezil HCL). See e.g. p[0023]: instant claims 1 and 2. At least one

pharmaceutically acceptable inactive ingredient is lactose. See e.g. p[0054] and [0077]:instant claims 1, 3, 8, 14(carrier), 20 and 21.

Claims 4-8 are directed toward a ratio of inactive to active ingredients having a range from 10:1 to 0.3:1 in claims 4, 3:1 to 1:1 in claim 5, and about 3:1 and about 1:1 in claims 6, 8 and 7. APPEL teaches that the solid dispersion contains from about 5 to 90% amorphous drug (see e.g. p[0037]) and the drug is about 60% to essentially all amorphous, which reads on the claimed ratio, e.g. if the drug is 50% then the ratio of inactive to active is 1:1. See p[0038]: instant claims 4-8.

Claim 9 is directed to the amorphous solid made by lyophilization, which is a product by process claim. The process of making the amorphous solid disclosed in claim 9 is not essential to a determination of patentability of the solid as disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

MPEP § 2113 states "[o]nce the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and

the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983)." Where the end products are the same, the process of making limitations do not have to be given weight in ex parte examination. See *Atlantic Thermoplastics Co. v. Faytex Corp.*, 23 USPQ2d 1481, 1490-91 (Fed. Cir. 1992) (product-by-process claims are treated differently for patentability purposes during ex parte examination in the USPTO than for infringement and validity purposes during litigation).

APPEL does not explicitly teach an amorphous form of lactose.

SEBHATU teaches the use of amorphous lactose in tablets. The amorphous form of lactose increases the tensile strength of the tablets in comparison to the crystalline form of lactose. See e.g. Abstract: instant claims 1, 3, 8, 20 and 21.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make an amorphous solid comprising a mixture of an amorphous active pharmaceutical, specifically donepezil HCL and at least one amorphous inactive ingredient, specifically amorphous lactose, as taught by APPEL in view of SEBHATU. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because of the beneficial effects of a higher tensile strength tablet that is formed by using amorphous lactose, as taught by SEBHATU. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,734,195 (WEISMAN) in view of SEBHATU et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to stable amorphous forms of donepezil hydrochloride in a pharmaceutical composition that can be a tablet. The instant invention requires the inactive ingredient/carrier, such as lactose, to be amorphous, which WEISMAN does not explicitly teach.

SEBHATU teaches the use of amorphous lactose in tablets. The amorphous form of lactose increases the tensile strength of the tablets in comparison to the crystalline form of lactose. See e.g. Abstract: instant claims 1, 3, 8, 20 and 21.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make an amorphous solid comprising a mixture of an amorphous active pharmaceutical, specifically donepezil HCL and at least one amorphous inactive ingredient, specifically amorphous lactose, as taught by WEISMAN in view of SEBHATU. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because of the beneficial effects of a higher tensile strength tablet that is formed by using amorphous lactose, as taught by SEBHATU. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Friday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-83738373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615